UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

20350 7590 04/07/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1,14,19 are objected to because of the following informalities: in each of claims 1,14,19 "...a patient interface device coupled to a patient's respiratory system..." and "...a mask coupled to the respiratory system of a patient..." should read –a patient interface device adapted to be coupled to a patient's respiratory system-- and --a mask adapted to be coupled to the respiratory system of a patient—in order to avoid any positive recitation of a human being and/or human anatomy as an element of the claimed combination. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1,2,14,17,19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al. (Acta Paediatr 89: 460-4, 2000) in view of Frank et al. ('477).

As to claim 1, Berggren et al. (fig.1) disclose a pressure assisted breathing system comprising: a patient interface device (see nasal mask) coupled to a patient's respiratory system; a respiratory circuit (conduit between humidifier and nasal mask) for providing gas communication between the pressure generating circuit and the patient interface device; and a nebulizer coupled to the respiratory circuit.

The difference between Berggren et al. and claim 1 is a pressure generating circuit for maintaining a positive pressure within the system.

While Berggren et al. (fig.1) do not expressly disclose a pressure generating circuit such circuitry is implicitly included inasmuch as pressure regulator is included upstream of the nebulizer for regulating the pressure of the breathable gas being supplied to the nebulizer. To the extent, if any, that Berggren et al. may not disclose a pressure generating circuit, resort is had to Frank et al., in a pressure assisted breathing system, that teach a pressure generating system (60,62) for maintaining positive pressure within the system for the purpose of providing breathable gas having sufficient pressure to maintain airway patency using CPAP.

It would have been obvious to modify Berggren et al. to include a pressure generating circuit because it would have provided breathable gas having sufficient pressure to maintain airway patency using CPAP as taught by Frank et al..

As to claim 2, Berggren et al. as modified by Frank et al. teach a flow generator (64) coupled with a pressure regulating device (fig.1 of Berggren and #64 of Frank et al.).

As to claim 14, Berggren et al. as modified by Frank et al. as discussed above with respect to claim 1 also teach a first gas conduit (e.g. conduit from tank 62 of Frank et al. to pressure/flow generator 62) connecting a flow generator to a pressure-regulating device (fig.1 of Berggren et al.) to provide a first high volume gas flow for generating a continuous positive airway pressure; a second gas conduit (conduit from nebulizer to nasal mask in fig.1 of Berggren et al.) connecting the first gas conduit to the patient

interface device for providing a second gas flow to the patient's respiratory system that is lower volume than the first gas flow.

As to claim 17, while Berggren et al. are silent as to the particular weight of the nebulizer, it is submitted that the weight of the particular nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular weight including 5 gms or less. One of ordinary skill would have recognized that a nebulizer for infants would have required less medicament and therefore a smaller nebulizer weight. Further, the particular sound pressure levels output by the nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular sound pressure level including 5dB or less. One of ordinary skill would have recognized the advantage if not need to employ a nebulizer that operates in a manner that does not wake a patient undergoing CPAP therapy during sleep.

As to claim 19, Berggren et al. as modified by Frank et al. as discussed above with respect to claim 1 also teaches a CPAP device comprising a source of pressurized gas (Frank et al. #62); a mask (fig.1 of Berggren et al.) coupled to the respiratory system of a patient; a flexible tube connecting the source of pressurized gas to the mask; and a nebulizer coupled to the mask and adapted to emit aerosolized medicament in close proximity to the patient's nose and/or mouth (fig.1 of Berggren et al.).

As to claim 20, Berggren et al. as modified by Frank et al. as discussed above with respect to claim 1 also teach the pressure generating circuit having a higher volume flow of gas than the respiratory circuit (i.e. the pressure and flow of gas from tank 62 of

Frank et al. is reduced significantly via pressure regulator (fig.1 of Berggren et al.) prior to entering the respiratory circuit and being delivered to a patient).

4. Claims 3,4,15,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al. (Acta Paediatr 89: 460-4, 2000) in view of Frank et al. ('477) as applied to claims 1,2,14,17,19,20 above, and further in view of Fink et al. (Aerosol Drug Therapy).

The difference between Berggren et al. as modified by Frank et al. and claim 3 is the pressure generating circuit comprising a first flexible tube and the respiratory circuit comprising a second flexible tube, and wherein the second flexible tube has a smaller diameter than the first flexible tube.

Fink et al. (figs.12-26 and 12-27), in a pressure assisted breathing system, teach a pressure generating circuit comprising a first flexible tube (see portion of corrugated tubing attached directly to the nebulizer) and a respiratory circuit comprising a second flexible tube (see portion of Y-shaped connected that is inserted within the corrugated tubing that is directly attached to the nebulizer), and wherein the second flexible tube has a smaller diameter than the first flexible tube. The use of corrugated tubing in the respiratory arts is well for its flexibility which permits patients to assume a variety of body positions and remain attached to the ventilator.

It would have been obvious to further modify the pressure generating circuit and respiratory circuits of Berggren et al. to employ any well known conduits including the corrugated conduits because it would have provided flexibility which permits patients to

assume a variety of body positions and remain attached to the ventilator as taught by Fink et al..

As to claim 4, the particular diameters of the corrugated tubing of Fink et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameters including 5mm or less. Tubing diameters would have depended upon the particular respiratory needs of a given patient; for example, an adult patient would require more pressure and flow rate than an infant and therefore larger capacity (i.e. diameter) conduits.

Claim 15 is substantially equivalent in scope to claim 3 and is included in Berggren et al. as further modified by Fink et al. for the reasons set forth above with respect to claim 3.

Claim 16 is substantially equivalent in scope to claim 4 and is included in Berggren et al. as further modified by Fink et al. for the reasons set forth above with respect to claim 4.

5. Claims 5-10,18,21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al. (Acta Paediatr 89: 460-4, 2000) in view of Frank et al. ('477) as applied to claims 1,2,14,17,19,20 above, and further in view of Davison (GB 2 272 389).

The difference between Berggren et al. as modified by Frank et al. and claim 5 a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit.

Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

While Berggren et al. is silent as to the particular type of nebulizer, it would have been obvious to employ any well known type of nebulizer including a vibrating aperture-type nebulizer because it would have facilitated the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose as taught by Davison et al..

As to claim 6, the reservoir of Davison et al. (page 2, lines 10-13) has a capacity equal to one unit dose of medicament.

As to claim 7, Davison et al. disclose a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claims 8-10, while Berggren et al. as further modified by Davison et al. are silent as to the particular weight of the nebulizer, it is submitted that the weight of the particular nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular weight including 5 gms or less. One of ordinary skill would have recognized that a nebulizer for infants would have required

less medicament and therefore a smaller nebulizer weight. Further, the particular sound pressure levels output by the nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular sound pressure level including 5dB or less. One of ordinary skill would have recognized the advantage if not need to employ a nebulizer that operates in a manner that does not wake a patient undergoing CPAP therapy during sleep.

As to claim 18, the reservoir of Davison et al. (page 2, lines 10-13) has a capacity equal to one unit dose of medicament.

As to claim 21, Berggren et al. as further modified by Davison et al. (fig.2) teach the aerosolized medicament is introduced by a vibrating aperture-type nebulizer coupled to the respiratory circuit.

As to claim 22, Davison et al. teach the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

As to claim 23, Davison et al. disclose a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Berggren et al. as further modified by Davison et al. as discussed above with respect to claim 1 also teach a method of delivering surfactant medicament to a patient's respiratory system (Berggren et al.) and entraining the aerosolized

surfactant into the respiratory circuit, whereby the patient breathes the aerosolized surfactant through the patient interface device (fig.2 of Davison et al.).

As to claim 25, Berggren et al. (page 461, col.1, lines 4-5) disclose the surfactant to be Curosurf which is a phospholipid.

As to claims 26 and 28, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient in Berggren et al. as further modified by Davison et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount including 6-18% and 10mg or less. Berggren et al. (page 461, col.1) disclose diluting surfactant prior to nebulization and Davison et al. teach a variable capacity reservoir (14) which controls the dose size; consequently, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Davison et al. teach the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

6. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren et al. (Acta Paediatr 89: 460-4, 2000) in view of Frank et al. ('477) as applied to claims 1,2,14,17,19,20 above, and further in view of Duarte et al. (Respiratory Care Clinics of North America 7:2, June 2001).

The difference between Berggren et al. as modified by Frank et al. and claim 11 is the nebulizer being located in the direct vicinity of the patient's nose, mouth or artificial airway.

Duarte et al. (page 239) teach the nebulizer being located in the direct vicinity of the patient's nose, mouth or artificial airway (i.e. 30cm) for the purpose of improving aerosol delivery.

It would have been obvious to further modify the nebulizer of Berggren et al. to locate it in the direct vicinity of the patient's nose, mouth or artificial airway because it would have improved aerosol delivery as taught by Duarte et al..

As to claim 12, fig.1 of Berggren et al. illustrates at least one gas conduit contained within the patient interface device (nasal mask) and the nebulizer is integrated (i.e. connected via a conduit) with the patient interface device.

As to claim 13, fig.1 of Berggren et al. illustrates the patient interface device comprising nasal prongs.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/883,115; claims 1-22 of copending Application No. 10/957,321; and claims 1-25 of copending Application No. 10/080,279. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the claims in each of these cases are drawn to a pressure assisted breathing system that includes the delivery of an aerosolized drug. With respect to the recitation of CPAP and/or NCPAP administration, these types of treatments are a subset of pressure assisted breathing systems. With respect to a particular type of medicament (e.g. surfactant, antibiotic), it is well known in the respiratory arts to employ an aerosolizer to deliver a variety of medicaments to patients via the respiratory system including surfactants and antibiotics. With respect to breath sensors to detect patient inhalation vs. exhalation, such sensors are well known in the art as exemplified by the prior art of record (e.g. Hakkinen) for the purpose of efficiently delivering medicament to a patient only during inhalation and not wasting medicament during exhalation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

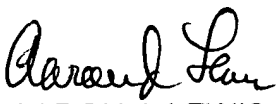
Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant pressure assisted breathing systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
March 13, 2006